



10-22-04

AF / 3764\$
PATENT
Attorney Docket No. 102.0010-01000
Customer No. 22882
JFW
A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Gary K. Michelson) Confirmation No.: 9274
Serial No.: 08/480,461)
Filed: June 7, 1995) Group Art Unit: 3764
For: INSTRUMENTATION FOR THE)
SURGICAL CORRECTION OF HUMAN) Examiner: Michael Brown
THORACIC AND LUMBAR SPINAL)
DISEASE FROM THE LATERAL)
ASPECT OF THE SPINE)

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

CERTIFICATE OF MAILING VIA U.S. EXPRESS MAIL

Express Mail Mailing Label No. ED149927455US

Date of Deposit: October 21, 2004

I hereby certify that:

1. Transmittal Form (in duplicate; \$72.00 additional claims fee charged to Deposit Account No. 50-1068)
2. Amendment
3. Request for Interference Under 37 C.F.R. § 41.202(a) with proposed count and 2 claim charts
4. Self-addressed return postcard receipt

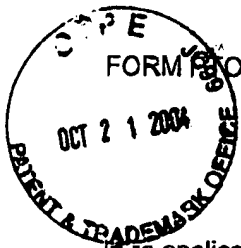
are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service with sufficient postage under 37 C.F.R. § 1.10 on the date indicated above and are addressed to:

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Date: October 21, 2004


Sandra L. Blackmon

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Attorney Docket No.: 102.0010-01000
Customer No. 22882
Express Mail Label No. ED149927455US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary K. Michelson, M.D.

Serial No: 08/480,461

Filed: June 7, 1995

For: INSTRUMENTATION FOR THE SURGICAL
CORRECTION OF HUMAN THORACIC AND
LUMBAR SPINAL DISEASE FROM THE
LATERAL ASPECT OF THE SPINE

Confirmation No.: 9274

Art Unit: 3764

Examiner: Michael Brown

Mail Stop AMENDMENT
Commissioner for Patent
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Transmitted herewith is an Amendment in the above-identified application.

- ☐ No additional fee is required.
- ☐ Applicant hereby requests a ***-month extension of time to respond to the above office action.
- ☒ Request for Interference Under 37 C.F.R. § 41.202(a) with proposed count and 2 claim charts are enclosed.

The fee has been calculated as shown below:

	(Col. 1) CLAIMS REMAINING AFTER AMENDMENT		(Col. 2) HIGHEST NUMBER PREVIOUSLY PAID FOR		(Col. 3) PRESENT EXTRA*	LG/SM \$ ENTITY FEE		ADD'L FEE DUE
TOTAL CLAIMS FEE	147	-	143	**	4	LG=\$18 SM=\$9	\$18	\$ 72.00
INDEPENDENT CLAIMS FEE	11	-	13	***	0	LG=\$88 SM=\$44	\$88	\$ 0
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIMS						LARGE ENTITY FEE = \$300 SMALL ENTITY FEE = \$150		\$ 0
TOTAL								\$ 72.00

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space. The "Highest Number Previously Paid For" (Total or Independent) is the highest number found from the equivalent box on Col. 1 of a prior amendment or the number of claims originally filed.

- ☒ An additional claims fee in the amount of \$72.00 is to be charged to Deposit Account No. 50-1068.
- ☐ A check in the amount of \$*** to cover the ***-month extension of time fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge any deficiencies of fees associated with this communication or credit any overpayment to Deposit Account No. 50-1068. A copy of this sheet is enclosed.
- ☒ Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
- ☒ Any patent application processing fees under 37 C.F.R. § 1.17

Respectfully submitted,
MARTIN & FERRARO, LLP

By: 
Amedeo F. Ferraro
Registration No. 37,129

Date: October 21, 2004

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Transmittal of Amendment1.DOC



PATENT
Attorney Docket No. 102.0010-01000
Customer No. 22882
Express Mail Label No. ED149927455US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
Gary K. Michelson)	Confirmation No.: 9274
Serial No.: 08/480,461)	
Filed: June 7, 1995)	Group Art Unit: 3764
For: INSTRUMENTATION FOR THE)	
SURGICAL CORRECTION OF HUMAN)	Examiner: Michael Brown
THORACIC AND LUMBAR SPINAL)	
DISEASE FROM THE LATERAL)	
ASPECT OF THE SPINE)	

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

REQUEST FOR INTERFERENCE UNDER 37 C.F.R. § 41.202(a)

Applicant hereby requests an interference with U.S. Patent No. 6,635,062 to Ray, III et al. (hereinafter, "Ray") pursuant to 37 C.F.R. § 41.202(a). A proposed count is attached hereto.

Claims 1 and 12-14 of Ray correspond to claims 1-4, respectively, of the proposed count. Claims 237-240 of the present application also correspond to claims 1-4 of the proposed count.

Claims 237-239 of the present application are a copy of claims 1, 12, and 13 of Ray. Claim 240 of the present application claims overlapping subject matter with claim 14 of Ray. A claim chart in accordance with 37 C.F.R. § 41.202(a)(3) comparing the claims of each party corresponding to the proposed count is attached hereto. The claims interfere within the meaning of 37 C.F.R. § 41.203(a) because the subject matter

of claims 237-240 of the present application would, if prior art, anticipate or render obvious the subject matter of claims 1 and 12-14, respectively, of Ray, and vice-versa.

Applicant will prevail on priority because the present application has an effective filing date more than 38 months prior to the earliest effective filing date of Ray. The present application claims priority to, and includes all the subject matter of U.S. Application No. 08/394,836 (the "parent application"), now U.S. Patent No. 5,772,661, filed February 27, 1995. The earliest effective filing date of Ray is April 9, 1998. Accordingly, the priority of the present application is *prima facie* earlier than the priority of Ray.

A claim chart in accordance with 37 C.F.R. §§ 41.202(a)(5) and (6) showing the written description in the current specification for each claim added to provoke an interference, and showing where the disclosure of the parent application filed February 27, 1995 provides a constructive reduction to practice within the scope of the interfering subject matter is attached hereto. The requirements of both 37 C.F.R. §§ 41.202(a)(5) and (6) are met in a single chart because the specification and drawings filed in the present application are a photocopy of the specification and drawings filed in the parent application, U.S. Application No. 08/394,836.

The Examiner is requested to declare an interference between the present application and U.S. Patent No. 6,635,062.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Request, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including

any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1068.

Respectfully submitted,

MARTIN & FERRARO, LLP

Date: October 21, 2004

By: 

Amedeo F. Ferraro
Registration No. 37,129

1557 Lake O'Pines Street, NE
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PROPOSED COUNT UNDER 37 C.F.R. § 41.202(a)(2)

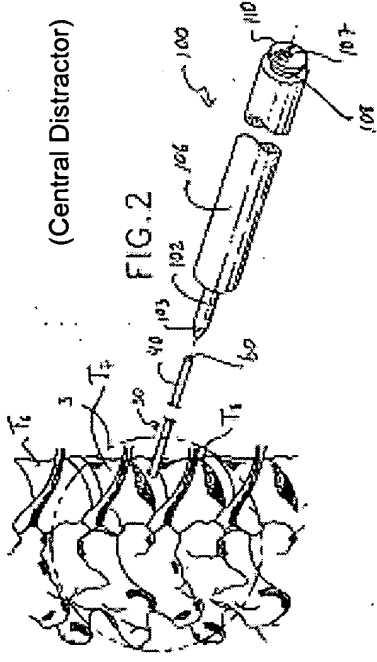
1. A spinal instrument assembly, comprising:
 - a central distractor having
 - a distractor tip coupled to a shaft, said distractor tip having upper and lower distraction surfaces defining a distraction height therebetween to maintain distraction of a spinal disc space;
 - a guide sleeve housing having a distal portion and a proximal portion, said guide sleeve housing defining a working channel in which said central distractor is centrally located, wherein said guide sleeve housing is positionable in an operative position with respect to the spinal disc space; and
 - a guide sleeve having a distal end and a proximal end, said distal end of said guide sleeve removably engageable to said guide sleeve housing.
2. The instrument assembly of claim 1, wherein said central distractor is withdrawable from the spinal disc space and said guide sleeve housing when said guide sleeve housing is in said operative position.
3. The instrument assembly of claim 1, wherein:
 - said guide sleeve has a first length extending proximally from said guide sleeve housing when engaged thereto;
 - said guide sleeve housing has a second length extending proximally from the operative site; and
 - a ratio of said first length to said second length is more than about 2:1.
4. The instrument assembly of 3, wherein said ratio is less than about 10:1.

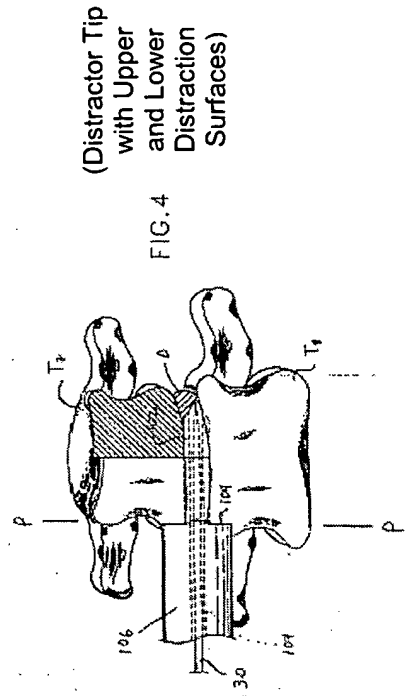
CLAIM CHART UNDER 37 C.F.R. § 41.202(a)(3)

Claim Count Number	Claims of Application No. 08/480,461	Claim of U.S. Patent No. 6,635,062
1	<p>237. A spinal instrument assembly, comprising: a central distractor having a distractor tip coupled to a shaft, said distractor tip having upper and lower distraction surfaces defining a distraction height therebetween to maintain distraction of a spinal disc space; a guide sleeve housing having a distal portion and a proximal portion, said guide sleeve housing defining a working channel in which said central distractor is centrally located, wherein said guide sleeve housing is positionable in an operative position with respect to the spinal disc space; and a guide sleeve having a distal end and a proximal end, said distal end of said guide sleeve removably engageable to said guide sleeve housing.</p>	<p>1. A spinal instrument assembly, comprising: a central distractor having a distractor tip coupled to a shaft, said distractor tip having upper and lower distraction surfaces defining a distraction height therebetween to maintain distraction of a spinal disc space; a guide sleeve housing having a distal portion and a proximal portion, said guide sleeve housing defining a working channel in which said central distractor is centrally located, wherein said guide sleeve housing is positionable in an operative position with respect to the spinal disc space; and a guide sleeve having a distal end and a proximal end, said distal end of said guide sleeve removably engageable to said guide sleeve housing.</p>
2	<p>238. The instrument assembly of claim 237, wherein said central distractor is withdrawable from the spinal disc space and said guide sleeve housing when said guide sleeve housing is in said operative position.</p>	<p>12. The instrument assembly of claim 1, wherein said central distractor is withdrawable from the spinal disc space and said guide sleeve housing when said guide sleeve housing is in said operative position.</p>
3	<p>239. The instrument assembly of claim 237, wherein: said guide sleeve has a first length extending proximally from said guide sleeve housing when engaged thereto; said guide sleeve housing has a second length extending proximally</p>	<p>13. The instrument assembly of claim 1, wherein: said guide sleeve has a first length extending proximally from said guide sleeve housing when engaged thereto; said guide sleeve housing has a second length extending proximally</p>

	from the operative site; and a ratio of said first length to said second length is more than about 2:1.	from the operative site; and a ratio of said first length to said second length is more than about 2:1.
4	240. The instrument assembly of 239, wherein said ratio is less than about 10:1.	14. The instrument assembly of 13, wherein said ratio is in the range of about 5:1 to about 10:1.

CLAIM CHART UNDER 37 C.F.R. §§ 41.202(a)(5) and (6)

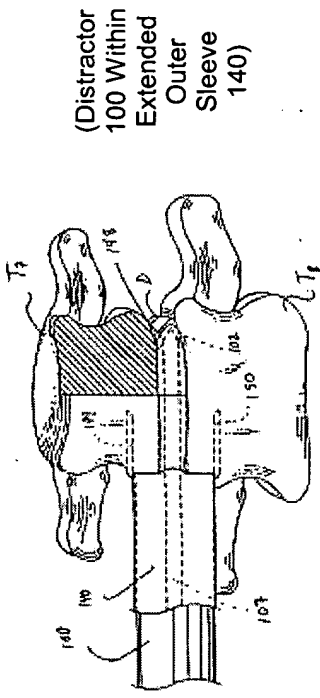
Claim Count Number	Claims of Application No. 08/480,461	Description and Location in Disclosure Providing Constructive Reduction to Practice
1	237. A spinal instrument assembly, comprising: a central distractor having a distractor tip coupled to a shaft,	<p>Applicant discloses a central distractor (distractor 100) that includes a distractor tip (penetrating portion 102) coupled to a shaft (barrel 106). (See Specification, page 17, lines 5-10; and Fig. 2).</p> <p>"The distractor 100 has a cylindrical barrel 106 that terminates at one end in a reduced diameter disc penetrating portion 102 that is essentially cylindrical, with further reduced diameter, bullet-shaped front end 103 to facilitate insertion into the disc space D. The distractor 100 has a shoulder portion 104 where the penetrating portion 102 extends from barrel 106...." (Specification, page 17, lines 5-10).</p> 
	said distractor tip having upper and lower distraction surfaces defining a distraction height of a spinal therebetween to maintain distraction of a spinal	The distractor tip (penetrating portion 102) disclosed by Applicant has upper and lower distraction surfaces defining a distraction height therebetween to maintain

<p>disc space;</p>	<p>distraction of a spinal disc space. (See Specification, page 18, line 26 to page 19, line 1; and Fig. 4).</p> <p>"Referring to Figures 4 and 5, once the distractor 100 is inserted into the disc space D, the penetrating portion 102 of the distractor 100 distracts the vertebrae T₇ and T₈ apart, such that the vertebrae T₇ and T₈ to either side of the penetrating portion 102 are forced into full congruence and thus become parallel, not only to the penetrating portion 102, but to each other. Because of the forced opposition of the vertebrae T₇ and T₈ to the penetrating portion 102 the distractor 100 will then come to lie absolutely perpendicular to the plane P of the lateral aspect of the thoracic spine S and absolutely parallel to the vertebral endplates, allowing optimal alignment for the procedure to be performed." (Specification, page 18, line 26 to page 19, line 1).</p> <div data-bbox="857 239 1258 930">  <p>(Distractor Tip with Upper and Lower Distraction Surfaces)</p> <p>FIG. 4</p> </div>
<p>a guide sleeve housing having a distal portion and</p>	<p>Applicant discloses a guide sleeve housing (distal end portion 1104) having distal and proximal portions. (See Specification, page 39, lines 26-28; and Fig. 35).</p>

<p>a proximal portion,</p>	<p>“...a hollow tubular member 1102 that is disengageable from the distal end portion 1104 of the convertible extended outer sleeve 100.” (Specification, page 39, lines 26-28).</p> <div data-bbox="412 315 790 852" data-label="Image"> </div>
<p>said guide sleeve housing defining a working channel in which said central distractor is centrally located,</p>	<p>The guide sleeve housing (distal end portion 1104) disclosed by Applicant defines a working channel in which the central distractor (distractor 100) is centrally located. (See Fig. 35). Applicant states in the specification that the extended outer sleeve shown in Fig. 35 is useable with the method described in relation to extended outer sleeve 140, with which the use of distractor 100 (see above) is described. (See Specification, page 40, line 32 to page 41, line 8; and Fig. 35).</p> <p>“It is appreciated that for surgery on the thoracic spine, while the method described above wherein the entire procedure is performed through the extended outer sleeve 140 is preferred, it is also possible to utilize the convertible extended outer sleeve 1100 when a full thoracotomy is</p>

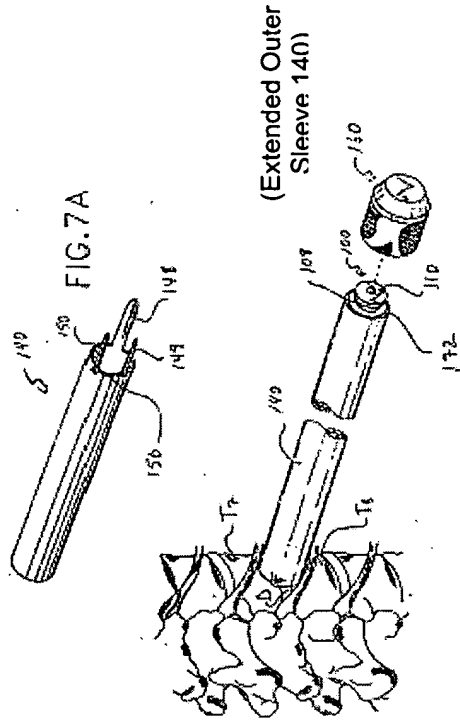
	<p>made to access the thoracic spine without having to work through the entire length of the extended outer sleeve. In this manner the surgeon may directly visualize and access the surgical site.</p> <p>Further, combining the features of the absence of any posterior intradiscal extended member with the convertible extended outer sleeve 1100 permits easy and direct access to the spinal canal for removal of any diseased discal material.” (Specification, page 40, line 32 to page 41, line 8).</p>
<p>wherein said guide sleeve housing is positionable in an operative position with respect to the spinal disc space; and</p>	<p>As disclosed by Applicant, the guide sleeve housing (distal end portion 1104) is positionable in an operative position with respect to the spinal disc space. (See Specification, page 35, lines 10-16 (relating to extended outer sleeve 1000); and page 40, lines 13-18). As stated in the specification, extended outer sleeve 1100 is inserted in the disc space as described for extended outer sleeve 1000. (Specification, page 39, line 34 to page 40, line 1).</p> <p>“The convertible extended outer sleeve 1100 is inserted in the disc space D and the adjacent vertebrae L₄ and L₅ as described above for the extended outer sleeve 1000.” (Specification, page 39, line 34 to page 40, line 1).</p> <p>“The extended outer sleeve 1000 is placed over the distractor 100 such that the posterior extension member 1022 is positioned at the posterior aspect of the spine and the anterior extension member 1020 is positioned at the anterior aspect of the spine. Once the extended outer</p>

		<p>"The hollow tubular member 1102 may be re-engaged to the distal end portion 1104 for inserting an implant I in the manner described above." (Specification, page 40, lines 19-21).</p>
2	<p>238. The instrument assembly of claim 237, wherein said central distractor is withdrawable from the spinal disc space and said guide sleeve housing is in said operative position.</p>	<p>The central distractor (distractor 100) disclosed by Applicant is withdrawable from the spinal disc space and the guide sleeve housing (distal end portion 1104) when the guide sleeve housing (distal end portion 1104) is in the operative position. (See Specification, page 23, lines 6-9 and 13-21; and Figs. 7-9).</p> <p>"In this way, the extended outer sleeve 140 is safely and assuredly inserted to its optimal depth, and no further, and rigidly secures the two adjacent vertebrae T₇ and T₈ as shown in Fig. 7." (Specification, page 23, lines 6-9).</p> <p>"The distractor 100 may now be removed from within the extended outer sleeve 140 since the extended outer sleeve 140 functions to maintain the distraction and alignment of the vertebrae T₇ and T₈. The extended outer sleeve 140 is held secure by the extension member 148 inserted within the disc space D and by the prongs 149 and 150 engaging the vertebrae T₇ and T₈.</p> <p>A distractor puller 200 is utilized to remove the distractor 100 in the direction of arrow Y from within the disc space D leaving the extended outer sleeve 140 in place." (Specification, page 23, lines 13-21).</p>



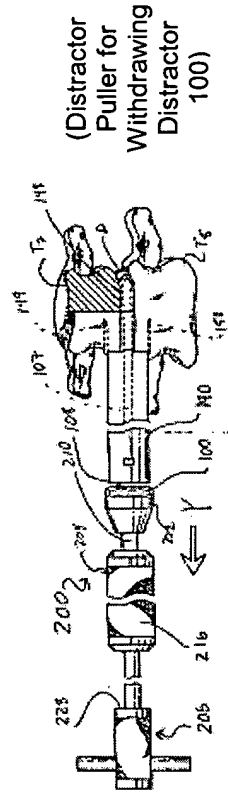
(Distractor
100 Within
Extended
Outer
Sleeve
140)

FIG. 7



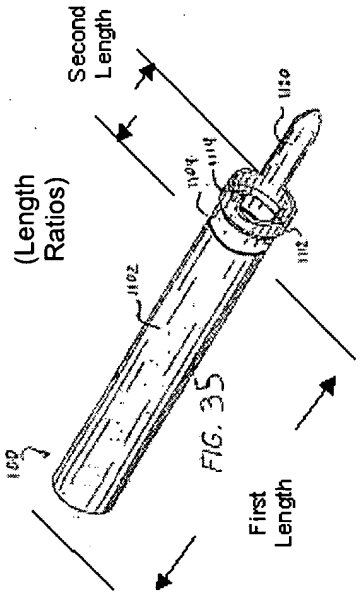
(Extended Outer
Sleeve 140)

FIG. 8



(Distractor
Puller for
Withdrawing
Distractor
100)

FIG. 9

3	<p>239. The instrument assembly of claim 237, wherein:</p> <p>said guide sleeve has a first length extending proximally from said guide sleeve housing when engaged thereto;</p> <p>said guide sleeve housing has a second length extending proximally from the operative site; and</p> <p>a ratio of said first length to said second length is more than about 2:1.</p>	<p>The guide sleeve (hollow tubular member 1102) disclosed by Applicant has a first length extending proximally from the guide sleeve housing (distal end portion 1104) when engaged thereto. (See Fig. 35). The guide sleeve housing (distal end portion 1104) disclosed by Applicant has a second length extending proximally from the operative site. (See Fig. 35). As can be seen in Fig. 35 of Applicant's drawings, the ratio of the first length to the second length is more than about 2:1. (See Fig. 35).</p> 
4	<p>240. The instrument assembly of 239, wherein said ratio is less than about 10:1.</p>	<p>As disclosed in Applicant's drawings, the ratio is less than about 10:1. (See Fig. 35).</p>